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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-0338)

Agency Forms Undergoing Paperwork Reduction Act Review

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Kimberly Lane, CDC Reports Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection

techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S. (OMB No. 0920-0338, exp. 9/30/2012) - Extension - Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description:

The oral use of smokeless tobacco (SLT) products represents a significant health risk. Smokeless tobacco products contain carcinogens which can cause cancer and a number of non-cancerous oral conditions, as well as leading to nicotine addiction and dependence. Furthermore, SLT use is not a safe substitute for cigarette smoking. Adolescents who use smokeless tobacco are more likely to become cigarette smokers.

The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH), has primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. HHS's overall goal is to reduce death and disability

resulting from the use of smokeless tobacco products and other forms of tobacco through programs of information, education and research.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 et seq., P. L. 99-252) requires each person who manufactures, packages, or imports smokeless tobacco products to provide the Secretary of Health and Human Services (HHS) with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products. CSTHEA further requires submission of the quantity of nicotine contained in each smokeless tobacco product. Finally, the legislation authorizes HHS to undertake research, and to report to Congress (as deemed appropriate) discussing the health effects of these ingredients.

HHS has delegated responsibility for implementing the required information collection to CDC's Office on Smoking and Health. Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies that are required to report ingredients added to other consumer products. Typically,

respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report. Respondents may submit the required information to CDC through a designated representative. The information collection is subject to strict confidentiality provisions.

Ingredient reports for new SLT products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted. Upon receipt and verification of the annual nicotine and ingredient report, OSH issues a Certificate of Compliance to the respondent.

There are no changes to information collection procedures or the estimated burden per response. There is an increase in total estimated burden due to an increase in the estimated number of respondents, from 11 to 13. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|-----------------------------------------------------------|----------------------------------------|--------------------|---------------------------------|----------------------------------------|-------------------------|
| Smokeless Tobacco Manufacturers, Packagers, and Importers | SLT Nicotine and Ingredient and Report | 13 | 1 | 1,713 | 22,269 |

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